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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221
27476	7590	03/29/2010	EXAMINER	
NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	
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			03/29/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/610,313	BARNETT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	J. E. ANGELL	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 January 2010.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 and 43-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,5-11,19-21,52 and 53 is/are rejected.

7) Claim(s) 2-4 12-18 22-40, 43-51 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

This Action is in response to the communication filed on 1/12/2010.

Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 1-40, 43-53 are currently pending and are addressed herein.

Applicants arguments set forth in the communication filed 1/12/2010 have been considered and Applicants arguments are persuasive, thus the previous rejections of record have been withdrawn. However, upon further consideration of claims, the following action is taken.

### ***Claim Objections***

1. Claims 1-40, 43-53 are objected to because of the following informalities:
2. Claims 1, 27, 52 and 53 contain both a reference to a sequence set forth in a particular Figure as well as an indication of the related sequence identifier (SEQ ID NO) in parenthesis.

Applicants are respectfully reminded that 2173.05(s) indicates:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Applicants are asked to delete the reference to the Figures from the claims and to leave the reference to the sequence identifiers (SEQ ID NO), but without the parenthesis.

3. Claim 20 includes the text "21." directly after the period. This appears to be a typographical error and Applicants are asked to delete the improper text from the claim.

4. Claim 39 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims **in the alternative only** (emphasis added). See MPEP § 608.01(n). In the instant case the phrase “any of claims 30-38” may not be solely in the alternative. Accordingly, the claim 39 has not been further treated on the merits. Applicants are asked to consider changing the phrase to “any one of claims 30-38”.

5. Claim 48 include the recitation “SEQ ID NO30, SEQ ID NO31 or SEQ ID NO32”, which is not an acceptable form of sequence identifier. Applicants are asked to change the text to “SEQ ID NO: 30, SEQ ID NO: 31 or SEQ ID NO: 32”.

6. Appropriate correction is required.

7. It is noted that claims 2-40, 43-53 are included in the objection because they depend on an objectionable claim.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 5-11, 19-21, 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16-22, 30-32 of U.S. Patent No. 7,211,659 (of record). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The instant claims are drawn to an expression cassette comprising a polynucleotide sequence operably linked to a promoter, wherein the polynucleotide sequence has at least 90% identity to the polynucleotide sequence presented in SEQ ID NO: 30, SEQ ID NO: 31 or SEQ ID NO: 32. It is noted that the word "has" is synonymous with "comprising". SEQ ID NO: 9 of the '659 patent has at least 90% identity with SEQ ID NO: 30, SEQ ID NO: 31 and SEQ ID NO: 32 (e.g., it has 99.2% identity with SEQ ID NO: 32). Furthermore, claim 1, 16-22 and 30-32 of the '659 patent are similar to the instant claims, but drawn to SEQ ID NO: 9. SEQ ID NO: 9 is at least 90% identical with SEQ ID NO: 30, SEQ ID NO: 31 or SEQ ID NO: 32, the indicated claims of the '659 patent comprise embodiments within the scope of the instant claims. Therefore, the instant claims are unpatentable on the ground of nonstatutory obviousness-type double patenting over claims 1, 16-22, 30-32 of U.S. Patent No. 7,211,659.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/  
Primary Examiner, Art Unit 1635